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## 510 (k) SUMMARY

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### DUAL LUMEN GASTRIC LAVAGE TUBE

Comparable to single tube Gastric lavage and stomach evacuator tubes.

Disposable, non-sterile tube for gastric lavage. Includes plastic tubing and connectors.

The lavage tube is used as a two way conduit from a lavage bag set to the stomach. The tube is made of a flexible PVC that is easy to insert and comfortable for the patient. Water is released from a fluid source and flows into the stomach. The larger the tube, depending on patient age, the quicker the lavage can be completed. Once in the stomach, the water is drawn back up the tube and into a drainage bag. Pill fragments from the overdose are part of the discharged fluid. The extra port in the lavage tube simply allows better "back and forth" flow. This is done by allowing air to quickly replace the fluid drawn out during drainage.

The dual lumen lavage tube is an improvement to Ethox's current tubes to allow a quicker lavage. The extra lumen is a small diameter airway that acts as a vent allowing the lavage fluid in the main tube to pass in and out of the stomach without any "vapor lock" action. It is a standard accepted feature used in the market. It will not change the function or the lavage procedure in any other way.

